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CLINICAL DIAGNOSIS OF BLADDER OUTLET OBSTRUCTION IN PATIENTS WITH BENIGN PROSTATIC ENLARGEMENT AND LOWER URINARY TRACT SYMPTOMS: DEVELOPMENT AND URODYNAMIC VALIDATION OF A CLINICAL PROSTATE SCORE FOR THE OBJECTIVE DIAGNOSIS OF BLADDER OUTLET OBSTRUCTION

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ABSTRACT

Purpose: We attempted to improve the method of objective clinical evaluation of patients with benign prostatic enlargement and lower urinary tract symptoms.

Materials and Methods: We compared the results of free uroflowmetry and transrectal ultrasound prostate size determination with those of pressure-flow analysis of bladder outlet obstruction in 871 consecutive elderly men.

Results: Maximal flow, prostate size, and post-void residual and voided volumes were correlated with bladder outlet obstruction to derive a clinical prostate score.

Conclusions: Clinical prostate score shows a superior correlation with bladder outlet obstruction than isolated objective parameters or symptom scores.

KEY WORDS: prostate, benign prostatic hypertrophy, urodynamics, bladder

Urodynamics are the gold standard in the diagnosis of bladder outlet obstruction in patients with benign prostatic enlargement but the clinical value of urodynamic investigation in daily practice has been criticized.[1] In the past there has not been a great effort to improve the clinical method of diagnosis of bladder outlet obstruction in elderly men, probably because of the acceptable success rate of therapy (generally transurethral resection of the prostate). However, the number of alternative treatments currently available is rapidly increasing but they do not seem to have high success rates. On the other hand, the threshold for seeking medical care for lower urinary tract symptoms seems to have decreased, possibly because of the availability of these alternatives. To take advantage of less invasive therapies selection criteria are needed. Improving clinical diagnosis may become useful for stratification of patients.

Urodynamics remain invasive, time-consuming and costly, and will not be implemented in daily routine practice for establishing the diagnosis in every elderly man with lower urinary tract symptoms. The value of urodynamics in predicting the outcome of surgery is limited. This conclusion is based on reports that patients without urodynamically confined bladder outlet obstruction are symptomatically the same after transurethral resection of the prostate compared to those with obstruction when all patients underwent surgery.[2–4]

However, we performed urodynamics routinely to assess all patients with benign prostatic enlargement for more than 2 years. The results of urodynamics were used to select patients who did not immediately require surgery for bladder outlet obstruction. In addition to complete urodynamics rectal ultrasound of the prostate and at least 1 spontaneous free uroflowmetry were done in all patients. Serum prostate specific antigen was measured and prostate biopsies were obtained when necessary. Furthermore, patients were asked to complete an International Prostate Symptom Score (I-PSS) and a Madsen symptom score questionnaire. We report the results of urodynamics in a large, referred but random group of patients with benign prostatic enlargement and lower urinary tract symptoms. The outcome of urodynamics was compared to the 2 symptom scores, and the free uroflowmetry results, post-void residual level and prostate size measurement by transrectal ultrasound. Based on these comparisons a clinical score was developed, which may prove valuable to predict the probable presence of bladder outlet obstruction.

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MATERIAL AND METHODS

We performed urodynamics in 871 consecutive men with benign prostatic enlargement and/or lower urinary tract symptoms in this retrospective study to analyze the grade of bladder outlet obstruction. Of the original 904 patients 33 were excluded from study due to age younger than 50 years.[5] However, 16 of the excluded patients (46.9%, mean age 46.7 years, range 41 to 49) had obstruction and the largest prostate was 95 cm.^{3} (mean 30.2). All patients were referred to our clinic because of prostatism. In 23 patients (2.6%) not excluded from analysis the prostate was between 17 and 20 cm.^{3}. A few patients (1 to 2%) able to perform free urine flow were unable to void during urodynamics due to inhibition and were excluded from analysis.

All patients were considered neurologically normal based on history, symptoms and physical examination (no motor, sensory or reflex deficits). Urine sediment and culture were negative at the time of urodynamics. Patients in acute retention were not included since retention is an almost absolute indication for surgery. However, patients with probably chronic large amounts of residual urine were included in the study when they were able to void during urodynamics.

A Dutch translation of the Madsen symptom score questionnaire was used, which has been available in The Netherlands since its publication in English. It has been successfully used in many international multicenter studies. The International Consensus Committee of the World Health Organization (WHO) international consultation on benign prostatic hyperplasia recommended translations of the I-PSS questionnaire.[5] The Flemish/Dutch translation is similar to the Dutch translation, which we have used since publication of the original American Urological Association-7 symptom score questionnaire.

To evaluate the structure of the prostate and prostate volume transrectal ultrasound was performed using a Combison 330 scanner with a 7.5 MHz. transducer for transrectal scanning (Multiplane 3-D VRW 77AK). The planimetric method was used to calculate prostate volume. Free uroflowmetry was done privately when the patient presented with a normal to severe urge to void. Flow was measured using a Urodyn 1000* flowmeter.

Urodynamics were performed with an 8F transurethral lumen catheter with an intravesical micro-tip pressure sensor. Before cystometry the bladder was emptied through the lumen of the transurethral catheter to quantify residual volume after free uroflowmetry. Abdominal pressure was recorded intrarectally with an 8F micro-tip sensor catheter. Pressure sensors were set at zero equals atmospheric pressure before placement. The bladder was filled with water at 20C at a filling speed of 50 ml. per minute with the patient supine. Filling was stopped when the patient expressed a strong urge to void, and voiding in the standing position was allowed privately.

Digitally stored urodynamic data were analyzed with a urodynamic analysis computer program developed at our department. To quantify bladder outlet obstruction pressure-flow graphs were fitted with a passive urethral resistance relation curve at the lowest pressure part of the graph. Minimal pressure during voiding and theoretical cross-sectional urethral lumen were derived using the passive urethral resistance relation curve.[6] Calculation of urethral resistance factor was based on the point of maximum flow (Q_{max}) and corresponding detrusor pressure.[7] Correction for artifacts was done as necessary. Urethral resistance factor of 29 cm. water or greater indicated bladder outlet obstruction.[8] The linear passive urethral resistance relation pressure-flow nomogram was used as a clinical classes scale: classes 0 and 1—no bladder outlet obstruction, 2 and 3—moderate obstruction and greater than 3—severe obstruction.

Statistical significance of the differences between mean values was tested with a paired samples t test when appropriate or a nonparametric Wilcoxon matched pairs signed ranks test as necessary. Differences between multiple group means were tested with Kruskal-Wallis 1-way analysis of variance. Pearson's coefficient of correlation was used for correlation analysis. Logistic regression analysis was performed to facilitate the development of a clinical score. A commercially available computer software package was used for statistical analysis.

RESULTS

Table 1 shows the average results of symptom scores, free uroflowmetry and ultrasound prostate volume determination. A self-administered I-PSS questionnaire was completed by 707 patients and a Madsen symptom score questionnaire was completed by 693. A free flow rate was recorded immediately before urodynamics in 815 patients and evaluable residual urine data after this voiding were obtained for 807. All urine flow values were included when voided volume was greater than 50 ml. Data on prostate size were evaluable for 813 patients.

The results of urodynamics for the group are also shown in table 1. Mean maximal flow during urodynamics (7.3 ml. per second) was significantly less than the mean free maximal flow (10.7 ml. per second, t test, p = 0.0001). The mean of the individual differences (free Q_{max} − urodynamic Q_{max}) was 3.44 ml. per second (range of differences −33 to 20, standard deviation 4.63). In 62.6% of the cases the individual difference was less than 4 ml. per second. Eight patients with extreme differences (−33 to −7 ml. per second) due to unrepresentative voiding during urodynamics were excluded from further analysis at this point. Five patients with a much better flow during urodynamics (differences of greater than 14 ml. per second) were included in the study. Although linear passive urethral resistance relation estimation of bladder outlet obstruction was done in another 31 patients, urethral resistance factor analysis was too unreliable for our study because the catheter slipped out during voiding or the uroflowmeter was disturbed. Therefore, these patients were excluded from urethral resistance factor analysis but included in linear passive urethral resistance relation analysis. Complete urodynamic data on bladder outlet obstruction were available in 821 cases.

There was no selective exclusion because of artifacts although patients who clearly had no obstruction tended to have larger differences in urodynamic flow rate, as we reported earlier.[10] Based on linear passive urethral resistance relation class 224 patients (28.2%) had no bladder outlet obstruction and based on urethral resistance factor analysis 304 (38.5%) had no obstruction (table 2). Six patients had obstruction on urethral resistance factor analysis but not according to linear passive urethral resistance relation class, and 85 (9.9%) had moderate obstruction according to linear passive urethral resistance relation class and obstruction on urethral resistance factor analysis. Two patients had no obstruction on urethral resistance factor analysis and severe obstruction according to linear passive urethral resistance relation class. We observed a significant difference between free and urodynamic maximal flows. Although 119 patients (15.8%) had improved maximal flow during urodynamics, in 632 (84.2%) maximal flow of pressure-flow voiding was less. We regard this difference (less than 4 ml. per second in 63% of cases) as systematic due to the transurethral catheter and the circumstances of the investigation. Since bladder outlet obstruction is quantified by the pressure-to-flow ratio, passive urethral resistance relation and linear passive urethral resistance relation analyses are not sensitive to maximal flow differences. Furthermore, pressure-flow analysis is calibrated for transurethral investigation.

Clinical parameters categorized according to urodynamic results are compared in tables 3 and 4. All parameters showed significant differences between the groups. However,

* Dantec Medical, Inc., Campbell, California.

TABLE 1. *Results of investigations in 871 cases*

Parameter	Mean (SD)
Pt. age	64.6 (8.6)
Madsen symptom score	12.5 (4.5)
I-PSS	17.5 (7.0)
Free maximal flow (ml./sec.)	10.7 (4.9)
Free flow vol. (ml.)	258 (152)
Post-void residual (ml.)	76 (129)
Prostate size (cm.^{3})	44.7 (22.3)
Urodynamics:	
Urodynamic capacity (ml.)	411 (138)
Maximal flow during urodynamics (ml./sec.)	7.31 (4.1)
Detrusor pressure at maximal flow (cm. water)	59.0 (29.5)
Urethral resistance factor	37.3 (19.5)
Minimal pressure during voiding (ml.)	30.6 (19.2)
Theoretical cross-sectional urethral lumen (mm.^{2})	3.5 (2.4)

TABLE 2. *Urodynamic classifications*

	Obstruction	No. Pts. (%)
Linear passive urethral resistance relation class:		
0/1	None	224 (28.2)
2/3	Moderate	341 (39.5)
4/5/6	Severe	256 (32.2)
Urethral resistance factor	None	304 (38.5)
	Present	486 (61.5)

TABLE 3. *Presence or absence of bladder outlet obstruction according to urethral resistance factor*

	Mean (SD)		p Value
	Obstruction (486 pts.)	No Obstruction (304 pts.)	
Pt. age	65.5 (8.4)	63.2 (8.8)	0.0005
Madsen symptom score	12.8 (4.4)	11.9 (4.3)	0.0196
I-PSS	17.8 (6.9)	16.6 (6.9)	0.0546
Free maximal flow (ml./sec.)	9.5 (3.8)	12.9 (5.3)	0.00001
Free flow vol. (ml.)	230 (136)	300 (165)	0.00001
Post-void residual (ml.)	78 (111)	50 (79)	0.00001
Prostate size (cm.^{3})	48.9 (24.3)	37.9 (15.0)	0.00001

TABLE 4. *Presence or absence of bladder outlet obstruction according to linear passive urethral resistance relation*

	Mean (SD)			p Value
	Severe Obstruction (256 pts.)	Moderate Obstruction (341 pts.)	No Obstruction (224 pts.)	
Pt. age	65.5 (8.6)	66.0 (8.2)	63.3 (8.8)	0.0003
Madsen symptom score	13.2 (4.2)	12.2 (4.6)	11.8 (4.2)	0.0090
I-PSS	18.6 (6.9)	17.0 (6.9)	16.4 (6.9)	0.0074
Free maximal flow (ml./sec.)	8.8 (3.6)	11.1 (4.7)	12.6 (5.2)	0.00001
Free flow vol. (ml.)	202 (116)	272 (150)	299 (169)	0.00001
Post-void residual (ml.)	89 (115)	61 (98)	50 (80)	0.00001
Prostate size (cm.^{3})	54.4 (27.3)	42.1 (17.8)	37.0 (15.0)	0.00001

the magnitude of the differences in symptoms between patients with and without bladder outlet obstruction was less than the differences on uroflowmetry or in prostate size. Analysis showed good correlation between both symptom scores and good correlation of the symptom scores with I-PSS quality of life (table 5).[5] There was no difference in I-PSS quality of life score between patients with and without obstruction (mean score overall 3.83, with obstruction 3.87 and without obstruction 3.75). Urodynamic correlations with clinical prostate score are shown in table 6. Figure 1 shows age and prostate size of all patients. There was a significant correlation of age with prostate size ($r = 0.2946$, $p = 0.001$). Table 7 shows average prostate size of distinct age groups in our study.

From the data in tables 3 and 4 we concluded that the existence of bladder outlet obstruction in these patients correlated with free uroflowmetry and prostate size at a high level compared to the number of symptoms. This conclusion does not imply that we consider measurement of symptoms or derivation of a reliable symptom score of lesser clinical importance. On the contrary, symptoms are the most frequent reason for the patient to seek medical care. The level of symptoms and their bothersomeness for the patient are important indicators of the need for medical intervention and important means to evaluate the success of intervention. However, we found poor correlation between grade of bladder outlet obstruction and level of symptoms. Therefore, we conclude that the decision to treat can be based on symptoms and/or bothersomeness of symptoms but, especially if different types of therapy are available, the treatment choice will be guided by the result of objective investigation(s). Since determination of prostate size and uroflowmetry with the quantification of post-void residual urine are simple measurements with low morbidity, we found it worthwhile to derive a scoring system for these clinical investigations, which could be used to predict the presence of bladder outlet obstruction in an elderly man with prostatic enlargement and lower urinary tract symptoms.

Development of the clinical prostate score. Table 6 shows that of the parameters maximal flow is the most important predictor of bladder outlet obstruction because it correlates well with urodynamic parameters. The correlation coefficients of prostate size, voided volume and post-void residual follow respectively. Logistic regression analysis with these 4 parameters versus obstruction or no obstruction confirmed that maximal flow was the best predictor for the presence of obstruction. The relative power or weight assigned to each parameter to predict bladder outlet obstruction was estimated on the basis of this logistic regression. Therefore, logistic regression analysis was not an end point of analysis. The analysis was merely used as a tool to construct the clinical score. The 4 parameters entered in regression analysis showed only poor individual statistical correlation (best correlation maximal flow with voided volume, $r^2 = 0.478$) and, therefore, logistic regression on these parameters was not confounded. The weight of the parameters derived from this analysis was used to assign points to the results of the various parameter values. The cutoff points of the classes were based on analysis of the histograms of the various parameters as well as on analysis of scatterplots of the parameters in relation to the quantifiers of bladder outlet obstruction.

Table 8 shows the parameters and the scoring points that we assigned to each parameter. Clinical prostate score, that is the total of the points achieved, was determined for 770 patients and compared to the urodynamic diagnosis of bladder outlet obstruction in 705. The possible range was 0 to 27 points and the average clinical prostate score was 10.4 (standard deviation 5.8) in this group.

There was a significant difference in clinical prostate score of patients with and without bladder outlet obstruction (mean 7.3 points for the 271 patients without and mean of 12.3 for the 434 with obstruction, t test, $p < 0.0001$). In figure 2 a urethral resistance factor of greater than 28 indicates obstruction. Referring to linear passive urethral resistance relation, mean values for no obstruction (7.5 points), moderate obstruction (9.6) and severe obstruction (13.7) showed statistically significant differences (Kruskal-Wallis test, $p < 0.00001$). Of the group 344 patients (48.8%) had a clinical prostate score of greater than 11 points of whom 247 (80.7%) had bladder outlet obstruction on urodynamics. Of the 250 patients (35.5%) with a clinical prostate score of less than 8 points 64% had no obstruction. Of the 55 patients with an I-PSS of 0 to 7 (mildly symptomatic) 26 (51%), of the 382 with an I-PSS of 8 to 19 (moderately symptomatic) 224 (61%) and of the 270 with an I-PSS of 20 or greater (severely symptomatic) 158 (63%) had obstruction.

TABLE 5. *Correlations*

	Maximal Flow During Urodynamics	Detrusor Pressure at Maximal Flow	Urethral Resistance Factor*	I-PSS Quality of Life Score†	Madsen Symptom Score	I-PSS
Pt. age	0.1505*	0.0663	0.1214		−0.0740	−0.0625
Total I-PSS	−0.0651	0.1074*	0.1090	0.5067	0.7378†	
Total Madsen symptom score	−0.0930	0.0988	0.1204	0.4369		
I-PSS quality of life score	−0.0430	0.0948	0.1043			
Urethral resistance factor	−0.5801†	0.8492†				
Detrusor pressure at maximal flow	−0.2540†					

* One-tailed test with significance at −0.01.
† One-tailed test with significance at −0.001.

TABLE 6. *Correlations*

	Detrusor Pressure at Maximal Flow*	Urethral Resistance Factor*	Minimal Pressure During Voiding	Theoretical Cross-Sectional Urethral Lumen*
Prostate size	0.2682	0.2894	0.2863*	−0.2016
Free maximal flow	−0.2475	−0.4208	−0.2122*	0.4581
Free flow vol.	−0.1983	−0.2944	−0.1954*	0.2145
Post-void residual	0.1545	0.1937	0.1075†	−0.1785
Clinical prostate score	0.3957	0.5272	0.3185*	−0.4582

* One-tailed test with significance at −0.001.
† One-tailed test with significance at −0.01.

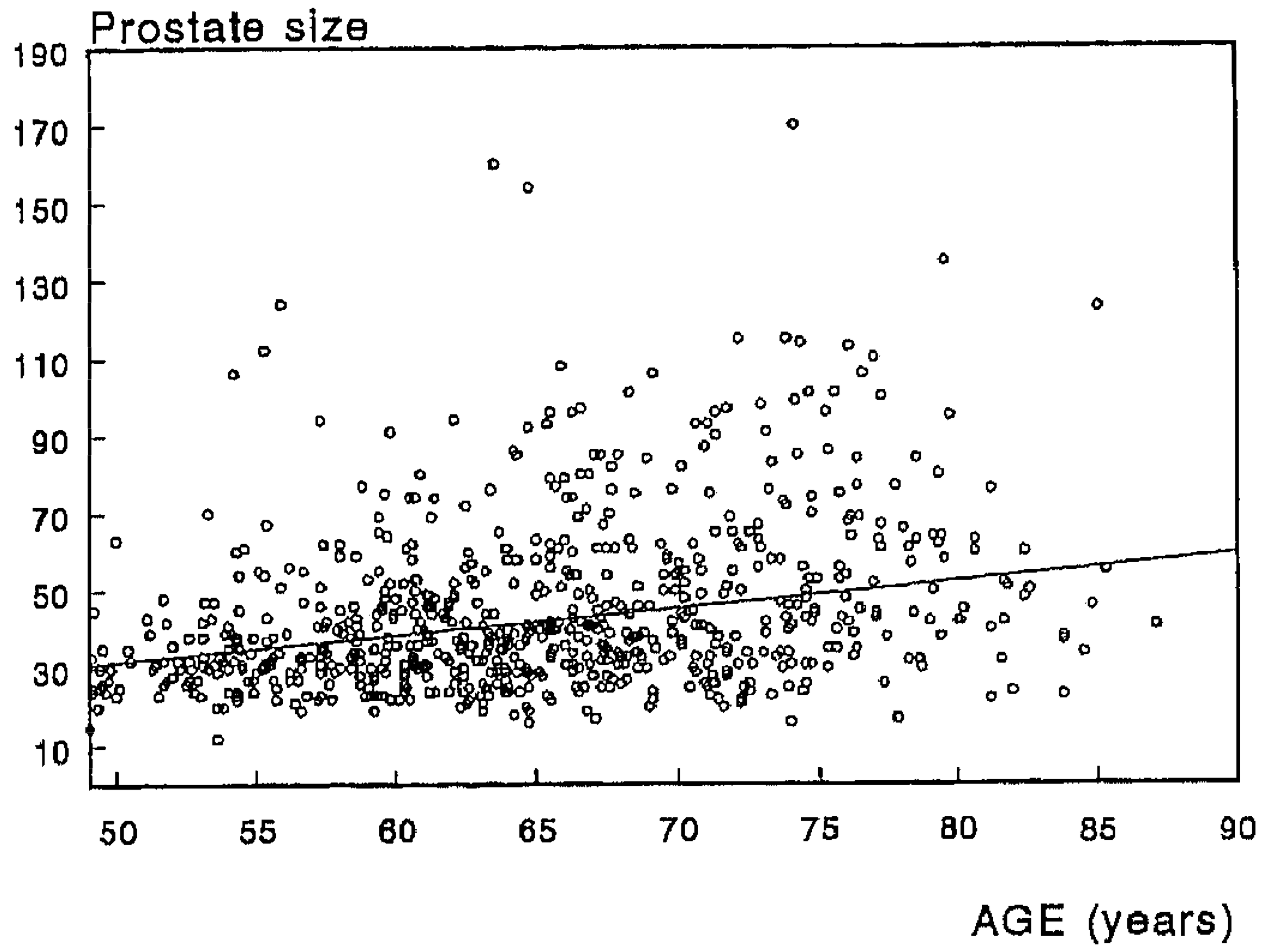

FIG. 1. Patient age and prostate size

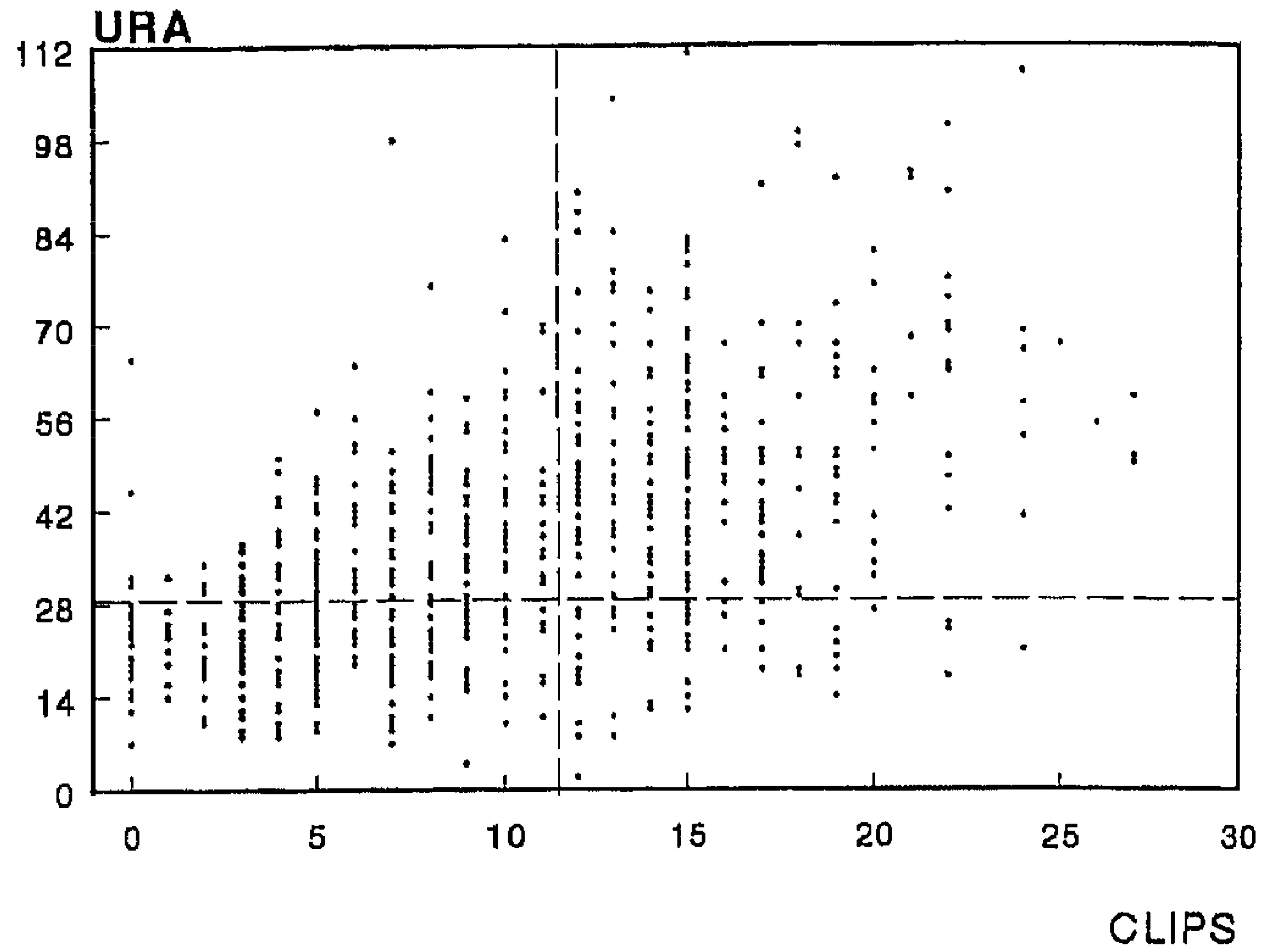

FIG. 2. Urethral resistance factor (*URA*) grade of obstruction and clinical prostate score (*CLIPS*).

TABLE 7. *Patient age and prostate size*

Age Greater Than	No. Pts.	Cm.^{3} Prostate Size (SD)
50	67	34.8 (13.4)
55	115	40.4 (17.8)
60	158	41.6 (20.4)
65	147	47.6 (20.1)
70	116	50.6 (26.6)
75	58	60.2 (25.0)
80	21	48.0 (22.0)
85	3	56.6 (09.9)

TABLE 8

	No. Points
Prostate size (cm.^{3}):	
Less than 30	0
30–60	3
Greater than 60	6
Free maximal flow (ml./sec.):	
Greater than 12	0
8–12	5
4–8	10
Less than 4	15
Post-void residual (ml.):	
Less than 30	0
30–100	2
Greater than 100	4
Voided vol. (ml.):	
Greater than 300	0
200–300	1
Less than 200	2

DISCUSSION

In a large group of men with benign prostatic enlargement and symptoms of lower urinary tract dysfunction we confirm a poor correlation between urodynamic findings and symptoms.[11–13] The correlation of the results of urodynamics with prostate size, as determined by transrectal ultrasound or free uroflowmetry, was better.[14, 15] The correlation of isolated objective parameters is generally believed to be too inaccurate for clinical decision making. However, we combined the results of these noninvasive investigations to derive a clinical scoring system. This score correlated well with the results of urodynamics. We excluded a limited number of patients from these analyses to prevent a retrospective observation bias. The procedures for prostate size estimation and uroflowmetry are routine, and results were not manipulated. Since the core of the diagnosis was urodynamics, some of these results have been excluded, as stated previously. Therefore, we have also included 1 urine flow value recorded just before urodynamics. Because there is a possibility that urine flow could improve on another occasion and almost 16% of the patients had better urine flow during urodynamics, we included these data. Furthermore, since urine flow can only improve with more attempts (a worse result shall not be used for analysis) the positive predictive value of the score will also only improve. However, prospective use of the score is needed to evaluate the validity of the scoring points.

It is important to emphasize that this score will never perfectly predict the presence or confirm the absence of bladder outlet obstruction. The sensitivity of clinical prostate score to detect obstruction when the lower score limit is 11 points is high in this group of patients (80.7%) but specificity is less (53.1%). Lowering the limit increases specificity, and only 11.8% of the patients with a clinical prostate score of less than 8 had severe bladder outlet obstruction on urodynamics.

The correlation between clinical prostate score and the results of urodynamics is superior to that between urodynamic bladder outlet obstruction and symptoms or symptom scores. For example, of the patients with mild or moderate symptoms 57.2% had obstruction. Also, the combination of clinical parameters in clinical prostate score results in a superior correlation with urodynamic results compared to the results of the separate clinical parameters, as shown by the coefficients of correlation of these parameters with the available obstruction parameters (table 6).

In general, clinical prostate score provides reassurance for clinicians since it refers to clinical experience. The older patient with a large prostate, small voided volume, low maximal flow and large post-void residual is the ideal candidate for the removal of obstruction. In our opinion this score and its good correlation with bladder outlet obstruction are mathematical evidence of this clinical experience. However, treating patients can never depend on the calculation of a score, and clinical prostate score must be interpreted as an indication of the relative value of each parameter or investigation in establishing the likelihood of obstruction without performing complete invasive urodynamics.

Others have studied symptoms and prostate size in a screened population.[16,17] Men were excluded from study when they had already been treated by a urologist and/or when they had a history of prostatic surgery. The prostates of the patients in our study were plus or minus 5 to 10 cm.[3] larger on average compared to those of the group that was screened, indicating that the exclusion of treated patients in the screening study may have caused bias toward smaller prostate size. Mean I-PSS of the reported screening group was 6.2 points and 30% had moderate or severe symptoms. Mean I-PSS quality of life score was 1.4, and there was a high correlation between I-PSS and quality of life. The correlation between I-PSS and uroflowmetry parameters was low.[16] The pattern of these correlations is comparable to our results, although prostate sizes, mean total I-PSS and bothersomeness (I-PSS quality of life score) were lower in the screening study. We conclude that our clinical patients differed significantly on average from the screened men only in the level of symptoms and less in objective parameters. The high correlation of I-PSS quality of life score and total I-PSS in both studies indicates that symptoms are predominantly influenced by bothersomeness and to a lesser extent by bladder outlet obstruction.[18]

WHO proposed recommendations concerning the diagnostic evaluation of patients presenting with symptoms suggesting prostatism. Uroflowmetry and measurement of residual urine are recommended diagnostic tests, while the assessment of prostatic size and shape is regarded as optional.[5] However, alternative treatments are not included in the WHO decision tree and reference values are not provided. The outcome of surgical treatment in relation to diagnostic investigations has been the subject of other studies.[4,19,20] Flow rate has been shown to predict outcome. The outcome was less favorable in patients with a preoperative maximal flow of 15 ml. per second or greater. Uroflowmetry is recommended for the evaluation of prostatism,[21] and we confirm an acceptable correlation of uroflowmetry with bladder outlet obstruction. Combining the results of uroflowmetry with those of other diagnostic tests, as shown in our study, improves diagnostic accuracy. We are convinced that the use of objective testing in referred patients with benign prostatic enlargement and lower urinary tract symptoms will augment the justification of treatment, and that clinical prostate score will be helpful in the selection of candidates for surgery or alternative therapies. Clinical prostate score can be used to select patients for surgical treatment when urodynamics are not available but it can also be used to select patients for urodynamics.

A recent study shows that patients with moderate bothersomeness of symptoms do better after transurethral resection of the prostate compared to watchful waiting.[22] Although reoperation for stricture was performed in 9.3% of the patients within 3 years of followup and 8.2% of the transurethral resection of the prostate procedures were regarded as unsuccessful, patients in the watchful waiting group had more retention and more infections. An increasingly large amount of residual urine was regarded as an indication for crossover to surgery in 8.7% of the cases, while 30 to 40% of those in the watchful waiting group had symptomatic improvement. Hypothetically these men could represent the 40% of patients without bladder outlet obstruction in our group with moderate symptoms. However, the symptomatic effect of watchful waiting in patients stratified according to urodynamic grade of bladder outlet obstruction is not yet established, although watchful waiting, when partially indicated by the results of urodynamics, can be a serious alternative.[23] The findings of Wasson et al[22] may confirm our results that solitary assessment of symptoms is ineffective for selecting candidates for alternatives to surgery. Therefore, we find it confusing that Oesterling, in debating the alternatives to treatment, referred to the study of Wasson et al and recommended selection of treatment based on symptoms, stating that there exist only relative indications to treat and that "the patient must be consulted."[24]

CONCLUSIONS

Prostate size and the results of free uroflowmetry measurement provide useful nonurodynamic indicators for the presence of bladder outlet obstruction. We used a combination of these investigations to derive a urodynamically validated, noninvasive, disease specific clinical prostate score. In comparison with analysis of symptoms or separate analysis of clinical evaluations, this clinical prostate score better predicts the presence of bladder outlet obstruction.

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